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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,445	03/09/2004	Robert E. Guisinger	K-00015-001	2414
25179	7590	01/04/2005		EXAMINER
A PATENT LAWYER CORP, PC R WILLIAM GRAHAM 22 S ST CLAIR ST DAYTON, OH 45402				COHEN, AMY R
			ART UNIT	PAPER NUMBER
				2859

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/796,445	GUIINGER ET AL.
	Examiner	Art Unit
	Amy R Cohen	2859

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 March 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/09/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1, 7 are objected to because of the following informalities:

Claim 1, line 6 "INA microorganism" should be "INA agent" as in the dependent claims.

Claim 7, line 3 "said transparent state" lacks antecedent basis in the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark (U. S. Patent No. 2,485,566) in view of Hanlon et al. (U. S. Patent No. 4,148,748).

Clark discloses a critical temperature indicator which provides an irreversible visual indication that the indicator has been exposed to a predetermined critical temperature, which includes a transparent housing (Col 2, lines 41-46); a temperature sensitive transformable material operably contained within said transparent housing which includes a mixture of water and INA microorganism (Col 2, lines 15-19 and Col 3, lines 5-26, wherein the indicator is formed with water as a solvent, and Col 4, line 65-Col 5, line 4) which is translucent prior to exposure of a predetermined temperature and is transformed upon being subjected to said predetermined temperature to render a substantially consistent opaque material thus precluding

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visibility therethrough and thereby providing a sure visible sign that said indicator has been subjected to said predetermined temperature (Col 2, lines 29-40, Col 3, lines 64-73, Col 4, lines 17-31).

Clark discloses the critical temperature indicator wherein said INA agent includes ice nucleating active (INA) microorganisms which contain a molecular structure to attract said water (Col 2, lines 15-24 and Col 3, lines 45-63).

Clark discloses the critical temperature indicator including a colored substrate (Col 3, lines 5-9) operable disposed with respect to said housing such that said colored substrate can be seen through said housing while said housing is in said transparent state and is substantially invisible when said material is opaque (Col 3, lines 5-26 and Col 4, lines 17-31).

Clark discloses the critical temperature indicator wherein said substrate is a colored strip contained within said housing (Col 3, lines 5-9).

Clark discloses the critical temperature indicator including a stabilizer for said INA microorganism (Col 3, lines 5-64).

Clark does not disclose the critical temperature indicator wherein the temperature sensitive transformable material includes latex.

Hanlon et al. discloses a critical temperature indicator (10) which provides an irreversible visual indication that the indicator has been exposed to a predetermined critical temperature, which includes a transparent housing (12); a temperature sensitive transformable material operably contained within said transparent housing which includes a mixture of water and latex (Col 2, lines 34-54) which is translucent prior to exposure of a predetermined temperature and is transformed upon being subjected to said predetermined temperature to render a substantially

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consistent opaque material thus precluding visibility therethrough and thereby providing a sure visible sign that said indicator has been subjected to said predetermined temperature (Col 2, lines 10-33).

Hanlon et al. discloses the critical temperature indicator wherein said latex includes particles having a diameter of less than about 0.05 microns (Col 3, line 61-Col 4, line 10).

Hanlon et al. discloses the critical temperature indicator wherein said latex is present in said material in an amount of from about 5 to 35 weight percent (Col 2, lines 49-54 and Col 3, lines 38-61).

Hanlon et al. discloses the critical temperature indicator wherein upon reaching said predetermined temperature the latex interacts and forms an opaque material (Col 2, lines 10-54).

Hanlon et al. discloses the critical temperature indicator wherein said latex includes one of acrylic, nitrile, polychloroprene, paraffin, polyethylene, waxes, styrene-butadiene, vinyl pyridine based, styrene polymers, styrene/butadiene copolymers, styrene/acrylic acid copolymers, vinyltoluene/tertiarybutyl styrene copolymers, vinylidene chloride/vinyl chloride copolymers or mixtures thereof (Col 2, lines 36-41).

Hanlon et al. discloses the critical temperature indicator including a colored substrate (20, cardboard is colored and not translucent) operable disposed with respect to said housing such that said colored substrate can be seen through said housing while said housing is in said transparent state and is substantially invisible when said material is opaque (Col 2, lines 10-33).

Hanlon et al. discloses the critical temperature indicator wherein said colored substrate forms part of backing to which said housing is sealably connected (Col 3, lines 20-29).

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Hanlon et al. discloses the critical temperature indicator wherein said backing has an exposed surface having a self adhesive material applied thereto (Col 3, lines 20-29).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the critical temperature indicator of Clark to include latex, as taught by Hanlon et al., since Hanlon et al. teaches that latex insures a reliable nonreversible destabilization of the colloidal dispersion upon freeze (Hanlon et al. Col 2, lines 49-54) thereby making the critical temperature indicator more accurate.

Regarding claims 12-14, 16-24, and 26-31, the rejection for claims 1-3, 5-11 contains the same subject matter as claims 12-14, 16-24, and 26-31, therefore, the rejection of claims 1-3, 5-11 applies for claims 12-14, 16-24, and 26-31.

Regarding claims 4, 15, and 25: Regarding the weight percentage of INA agent: Clark and Hanlon et al. disclose a critical temperature indicator having a percentage of INA agent (Clark, Col 3, lines 45-55 and Col 4, lines 1-9) but does not disclose a particular value for this parameter. However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide a weight percent of from about 0.01 to 1.0 weight percent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the "optimum range" involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the critical temperature indicator of Clark and Hanlon et al., to be of about 0.01 to 1.0 weight percent INA agent in order to ensure an accurate and rapid indication of the predetermined critical temperature.

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Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents disclose temperature indicators Wallach (U. S. Patent No. 6,495,368), Pereyra et al. (U. S. Patent No. 5,964,181), Goldsmith (U. S. Patent No. 5,306,466), Tarcha et al. (U. S. Patent No. 5,252,459), Jalinski (U. S. Patent No. 5,182,212), Sutton et al. (U. S. Patent No. 4,997,772), Klibanov et al. (U. S. Patent No. 4,826,762), and Orser et al. (U. S. Patent No. 4,464,473).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy R Cohen whose telephone number is (571) 272-2238. The examiner can normally be reached on 8 am - 5 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego F. Gutierrez can be reached on (571) 272-2245. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ARC
December 13, 2004



Diego Gutierrez
Supervisory Examiner
Tech Center 2800